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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,221	12/13/2001	Nathan S. Lewis	1034345-000091	9894

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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1753

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/017,221

Applicant(s)

LEWIS ET AL.

Examiner

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Rejection under 35 U.S.C. §112, first paragraph

1. Applicant's arguments filed December 13, 2006 ("Arguments") have been fully considered but they are not persuasive.

Applicants refer to a number of references at the bottom of page 6 of the Arguments, bridging to page 7, as evidence that their invention is enabled for compounds other than alcohol, especially DAN and proteins. As a first matter,

Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. In *re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. In *re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also *United States v. Teletronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the

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invention from the disclosures in the patent coupled with information known in the art without undue experimentation.”). A patent need not teach, and preferably omits, what is well known in the art. In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); and Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). [emphasis by the Examiner]

See MPEP 2164.01

Drummond et al. was published in October of 2003, almost two years after the filing date of the instant application and more than five years after the earliest priority document. Most of the references cited in the endnotes of Drummond were published in the year 2000, which is after the filing date of the parent application 09/291,932, of which the instant application is a continuation. Thus, assuming *arguendo* that Drummond supports Applicants' position as alleged in content, it is unpersuasive in traversing the scope of enablement rejection because it does not appear to show what was well known in the art *at the time of the invention*. Furthermore, as discussed on page 2 of the Office action of June 14, 2006 ("Office action") Drummond does not support Applicants' position, but teaches away from it, as Drummond does not disclose a differentially responsive sensor but a very narrowly responsive sensor as it comprises a recognition layer for hybridizing DNA. Also, as noted in the Office action, Drummond states that reliable operation of mass-based transducer is a *technical challenge*.

All of the patents listed at the top of page 7 of the Arguments were published after Applicants' filing date. Furthermore, only one of them, US 6,68,230 B2, has a filing date earlier than the filing date of the instant application. This filing date is also after the

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filing dates of both of Applicants' priority documents. Thus, as with Drummond, these references do not show what would have been known to one with ordinary skill in the art at the time of the invention. Moreover, none of these references discloses detecting complex biomolecules, such as DNA or proteins, let alone determining their specific activity or function. US 6,477,749 is totally unrelated to the claimed invention as it is directed to a *magnetic tack*.

Since in traversing an enablement rejection references outside the original disclosure are to be used to only show what was well known or obvious (needing little experimentation) to one with ordinary skill in the invention at the time of the invention, do Drummond and the US patents listed by Applicants in Applicants' view mean that their invention is obvious?

At the bottom of page of the Arguments Applicants again make the mistake of the fallacy of composition, which was discussed on page 3 of the Office action of May 10, 2005. Applicants argue that because their disclosed sensor can determine a function or activity of a gaseous alcohol and that these alcohol comprises chemical bonds and side groups, that the sensor can then inherently determine the function or activity of any chemical or biomolecule, no matter how complex or in what state, because they also have chemical bonds and side groups. Applicants have not demonstrated that the capabilities of a sensor array of resistance sensors with regard to a gaseous small alcohol molecules can be reasonably expected to extend to DNA or proteins in solution in an arbitrary array of optical, mechanical, magnetic, and electrical sensors.

With regard to the Examiner's arguments based on Old Yellow Enzyme, Applicants argue, "Simply put, just because the function of an enzyme is not known using other techniques does not mean the claimed invention is not enabled." See page 8 of the Arguments. While it does not necessarily follow that Applicants' invention is not enabled, it strongly suggests so. It is interesting that Applicants, in order to refute the Examiner's arguments, have not submitted a Declaration showing that their claimed sensor array is enabled to determine the function of Old Yellow Enzyme.

On the bottom of page 8, bridging to and through the first full paragraph on page 9 of the Arguments Applicants essentially just opine that they should not be limited by particular analyte, sensor type, or probed property.

In the bottom paragraph on page 9 of the Arguments state, "The array of sensor to measure a class of analytes (e.g., DNA, Enzymes, Chemical Compounds) can be developed empirically without undue experimentation so long as the same array is used with the base library and the unknown analyte. For example, mass can be measured on one sensor-type, hybridization on another, changes in absorption/adsorption to a resistive polymer sensor etc." Similarly, in the second full paragraph on page 10 of the Arguments Applicants argue that their invention is not comprised of homogeneous/identical sensors. First, it is very noteworthy that in Applicants' *sole* example, in which the analytes are simple alcohols, the sensor array *does not* comprise an array of different differentially responsive sensors, but instead comprises an array of the same type of differentially responsive sensors – resistive sensors comprising different amounts of non-conducting polymers and carbon particles. See [0048]-[0050]

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of the specification. Second, hybridization sensors are not differentially responsive. They are highly specifically responsive. The analyte must have a complementary sequence in order to hybridize with the hybridization probe on the sensor. Third, the Examiner has not found a mention of mass sensors or hybridization sensors in the original disclosure. Fourth, it is also noteworthy that the Applicants' specification does not refer to a sensor array of *different* differentially responsive sensor, only original claim 1 does. The specification only appears to disclose sensor arrays of the same type of sensors (e.g., resistance or optical) sensors each having different response behavior to the other sensors. See, for example, [0012]-[0014]. Last, the specification makes quick mention of optical and sound sensors ([0047]). Applicants are invited to outline how one with ordinary skill in the art at the time of the invention, using Applicants' disclosure, would create a sensor array comprising optical, sound, and resistance sensors to perform with DNA or protein as claimed in claim 16.

Applicants state that the Examiner is being inconsistent by making a rejection of lack of enablement and also a rejection under 35 U.S.C. §103(a) (based on Ballentine). However, the Examiner is not inconsistent, because the rejection under 35 U.S.C. §112, first paragraph, is a scope of enablement rejection. It is not the Examiner's position that Applicants' claimed invention is not enabled at all, but that it is enabled for analytes of a certain type (gaseous alcohols) and for certain sensor types (resistance sensors).

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Rejection under 35 U.S.C. §103(a)

As argued in the rejection of claim 16 the missing element of "not including the analyte of interest, ..." is obvious over Ballantine because it discloses using discriminant functions to classify samples as to their strengths as hydrogen bond donor or hydrogen bond acceptor (an activity or chemical property). As for no party having published or described the elements of Applicants' claimed invention since the publication of Ballantine this may be because no party has figured out how to enable such an invention.

For the reasons set forth above all of the rejections are maintained.

Final Rejection

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Nogueroles
Primary Examiner
AU 1753
February 22, 2007